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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,418	02/23/2004	Jerome P. Ranch	0930C	1807
27310	7590	03/18/2005	EXAMINER	
PIONEER HI-BRED INTERNATIONAL INC.			ROBINSON, KEITH O NEAL	
7100 N.W. 62ND AVENUE			ART UNIT	
P.O. BOX 1000			PAPER NUMBER	
JOHNSTON, IA 50131			1638	

DATE MAILED: 03/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/784,418

Applicant(s)

RANCH ET AL.

Examiner

Keith O. Robinson, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/23/2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date June 2, 2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claim Objections

1. Claim 1 is objected to because of the following informalities: (a) line 1 contains the phrase "an embryo", it is suggested that this phrase read ---a maize embryo---, (b) line 2 contains the phrase "a different plant", it is suggested that this phrase read ---a different maize plant---, (c) line 3 has the phrase "an embryo", it is suggested that the phrase read ---a maize embryo---, (d) line 7 has the phrase "using same experimental conditions", it is suggested that the phrase read ---using the same experimental conditions---. Appropriate correction is required.

Drawings

2. Figures 1, 2, 4a, 4b, and 5 are objected to because they are not decipherable due to large areas being blacked out. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several

views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112, first paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims read on a method of developing an embryo having increased transformation efficiency comprising crossing a Hi-II maize plant to any different plant to obtain an embryo; wherein said embryo has increased transformation efficiency when compared to a transformation efficiency of an embryo from any different plant and wherein said Hi-II plant is a male (claim 2) or female (claim 3) parent.

The specification lists several elite genotypes that may be used as a different plant to be crossed with Hi-II maize plants (see page 7, line 13 to page 11, line 29 and page 38, Table 1). The specification, however, only describes the elite maize genotypes PHN46, PHP18, PHT05, PH21T, PHP02, ASKC27, PH24E, PH05F, PH09B, and PHAA0 as different maize plants that can be crossed with Hi-II maize plants and the hybrids derived from such a cross having increased transformation frequency and does not give a written description of any other kind of plants as broadly claimed (see page 38, lines 4-15 and Table 1; page 39, Tables 2 and 3; page 40, Table 4). There is no written description of the elite maize genotypes used as the different maize plant to be crossed with Hi-II maize plants in terms of their genetic, morphological, and/or physiological background.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials". *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not description of that material". *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus". *Id.*

See MPEP Section 2163, page 156 of Chapter 2100 of the August 2001 version, column 2, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

Given the failure of the specification to describe the different plant, methods of using it are also inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention. See the written description guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 4, 2001/ Notices: pp. 1099-1111.

5. Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims read on a method of developing an embryo having increased transformation efficiency comprising crossing a Hi-II maize plant to any different plant to obtain an embryo; wherein said embryo has increased transformation efficiency when

compared to a transformation efficiency of an embryo from any different plant and wherein said Hi-II plant is a male (claim 2) or female (claim 3) parent.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

The specification only teaches the use of elite maize genotypes PHN46, PHP18, PH21T, ASKC27, PH24E, PH05F, PH09B, and PHAA0 as different maize plants that can be crossed with Hi-II maize plants and the hybrids produced from such a cross having increased transformation frequency and does not teach or provide evidence of any other kind of plants that can be crossed with Hi-II as broadly claimed (see page 38, lines 4-15 and Table 1; page 39, Tables 2 and 3; page 40, Table 4). There is no guidance provided regarding the genetic, morphological, and/or physiological background of the elite maize genotypes used as the different maize plant to be crossed with Hi-II maize plants in terms of their genetic, morphological, and/or physiological background, or of their degree of relatedness to each other. Thus, one skilled in the art would not know how to make and/or use the invention as it is broadly claimed.

The art teaches that the genetic variation among individual progeny of a breeding cross allows for the identification of rare and valuable new genotypes but that these

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genotypes are neither predictable nor incremental in value, but rather the result of manifested genetic variation combined with selection methods, environments and the actions of the breeder (Kevern US Patent 5,850,009, column 4, lines 41-46); therefore, Applicant has not taught how to make and use the myriad of different hybrids that may be produced from the result of manifested genetic variation combined with selection methods, environments and the action of the breeder without undue trial and error experimentation.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

7. Claim 1 is rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Zhao et al (U.S. Patent 5,981,840, November 9, 1999).

The applied reference has a common inventor (Zuo-Yu Zhao) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this

application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The claims read on a method of developing an embryo that has increased transformation efficiency comprising crossing a Hi-II maize plant to a different plant to obtain an embryo that has increased transformation efficiency compared to a transformation efficiency of an embryo from said different plant.

Zhao et al teach the use of Hi-II maize plants in a method of developing an embryo that has increased transformation efficiency (see column 7, lines 44-63 and column 17, line 35 to column 18, line 18).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhao et al (U.S. Patent 5,981,840, November 9, 1999).

The claims read on a method of developing an embryo that has increased transformation efficiency comprising crossing a Hi-II maize plant to a different plant to obtain an embryo that has increased transformation efficiency compared to a transformation efficiency of an embryo from said different plant, wherein the Hi-II maize plant is a male parent or female parent.

Zhao et al teach Hi-II maize plants that were cross pollinated with sister plants, which would infer that the Hi-II maize plants could be either male or female as the reference does not state that reciprocal crosses cannot be made. Thus, the reference is interpreted to teach Hi-II maize plants as either a male or female parent.

It would have been obvious to one of ordinary skill in the art to use the teachings of Zhao et al and to use the Hi-II maize plants as either a male or female parent.

Thus, the claimed invention as a whole was *prima facie* obvious over the teachings of the prior art.

Conclusion

10. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith O. Robinson, Ph.D. whose telephone number is 571-272-2918. The examiner can normally be reached on Monday - Friday 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, Ph.D. can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Keith O. Robinson, Ph.D.

March 8, 2005

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read "David H. Kruse", written over the printed name and title.